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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/662,358	09/16/2003	Sang Yup Lee	Q77446	2373

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EXAMINER

WALICKA, MALGORZATA A

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 12/02/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/662,358

Applicant(s)

LEE ET AL.

Examiner

Malgorzata A. Walicka

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Aug.31, 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 6-14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 6-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>09/16/03</u> . | 6) <input type="checkbox"/> Other: _____ |

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The Amendment filed on August 31, 2005 is acknowledged. Claims 1-5 have been cancelled; new claims 11-14 have been added; claims 6-10 have been amended. Claims 6-14 are pending and under examination.

DETAIL ACTION

1. Objections

1.1. Specification

The amendments to the specification are acknowledged.

1.2. Claims

Objection to claim 7 is withdrawn, because the language of the claim has been corrected.

Claims 1-14 are objected to for using the noun "bacteria" as meaning "bacterium", which is a singular form of this noun in English.

2. Rejections

2.1. 35 USC section 102

Rejection of claim 1-3 and 5 made under 35 U.S.C. 102(b) in the Office Action of June 2, 2005 (previous action) is moot because the claims have been cancelled.

2.2. 35 USC section 103

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Claim 6-10 were rejected under 35 U.S.C. 103(a) is the previous Office Action. This rejection is now withdrawn, because because Applicant's arguments are found persuasive. The article of Tsuge et al. used in the rejection does not teach *E. coli* having *fadB* gene deleted.

2.3. 35 USC section 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claim 9-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims recite the phrases: "under conditions promoting production of MCL-PHA "and conditions such that". These phrases are not defined in the specification or claims and therefore indefinite. An indefinite phrase renders the claim indefinite.

Claim 7 is lacking antecedent for the phrase "wherein said recombinant vector comprises PHA synthase gene." The vector of claim 6 from which claim 7 depends comprises only a polynucleotide encoding amino acids 1-681 of SEQ ID NO: 1. In addition, the claim broadens and not limits the scope of the base claim 6. In claim 6, the vector used for transformation comprises a polynucleotide encoding SEQ ID NO: 1. Claim 7 cannot introduce the second gene to this vector.

2.4. 35 USC section 112, first paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Written description

Claim 9-10 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The amended claim 9 recites the limitation "under conditions promoting production of MCL-PHA". This limitation is absent from the specification and the claims as originally filed, therefore, this limitation consists a new matter. In addition, claim 10 recites a limitation "under conditions such that 3-hydroxyoctanoate (3HO) monomers and 3-hydroxydecanoate (3HD) monomers in the MCL-PHA produced each comprise more than 30% of monomers comprising the MCL-PHA produced". Neither the original claims nor the specifications teaches "such conditions that". Therefore this limitation consists a new matter. Hence, claims 9-10 are rejected because one having skills in the art is not convinced that Applicants were in possession of the claimed invention at the time the application was filed.

Claim 7 rejected, because neither the specification nor claims teach a vector comprising a polynucleotides encoding SEQ ID NO: 1, and a PHA gene. This is a new

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matter, and one skilled in the art is not convinced that Applicants were in possession of the claimed invention at the time the application was filed.

Claims 6-14 are rejected because they are directed to an extremely large genus of transformed bacteria and methods of their use, wherein the scope of said genus encompasses:

- a) any known and unknown bacterium which lacks a functional *fadB* gene and is transformed to comprise SEQ ID NO: 1, and
- b) wherein said bacterium is transformed with a PHA synthase gene from any natural or man-made source.

Applicants disclose only two species of the claimed genus, i.e.:

- 1) *E. coli* wherein the *fadB* gene was deleted by applicants, and *maoC* gene of *E. coli* (SEQ ID NO: 1) and *phaC2_{Ps}* gene of *Pseudomonas* species were introduced, and
- 2) *E. coli* wherein the *fadB* gene was deleted, *maoC* gene was deleted and *maoC* gene of *E. coli* (SEQ ID NO: 1) and *phaC2_{Ps}* gene of *Pseudomonas* species were introduced.

Applicants do not disclose bacterial cells used for transformation except for *E. coli*. Also any gene whose origin is different than stated under 1) and 2) was not involved in manipulations. *E. coli* and its *fadB* and *maoC* genes do not provide identifying characteristics of enormous genus of bacteria and their *fadB* genes.

Similarly, PHA synthase gene *phaC2_{Ps}* of *Pseudomonas* species used by Applicants does not provide identifying characteristics of the whole genus of PHA genes

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from all natural and man-made sources. In conclusion, one skilled in the art is not convinced that at the time the application was filed applicants were in possession of the broadly claimed invention.

Scope of enablement

Claim 6-14 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for:

- 1) *E. coli* wherein the *fadB* gene was deleted by applicants, and *maoC* gene of *E. coli* (SEQ ID NO:1) and *phaC2_{Ps}* gene of *Pseudomonas* species were introduced,
- 2) *E.coli* wherein the *fadB* gene was deleted, *maoC* gene was deleted and *maoC* gene of *E. coli* (SEQ ID NO:1) and *phaC2_{Ps}* gene of *Pseudomonas* species were introduced,

and a method of their use for production of PHA, does not reasonably provide enablement for

- a) any known and unknown bacterium which lacks a functional *fadB* gene and is transformed to comprise SEQ ID NO: 1, and
- b) wherein said bacterium is transformed with a PHA synthase gene from any natural or man-made source.

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. The scope of the claims encompasses all bacteria and all

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PHA synthase genes, from any natural and man made sources. The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Otherwise, undue experimentation is necessary to make the claimed invention. Factors to be considered in determining whether undue experimentation is required, are summarized *In re Wands* [858 F.2d 731, 8 USPQ 2nd 1400 (Fed. Cir. 1988)]. The Wands factors are: (a) the nature of the invention, (b) the breadth of the claim, (c) the state of the prior art, (d) the relative skill of those in the art, (e) the predictability of the art, (f) the presence or absence of working example, (g) the amount of direction or guidance presented, (h) the quantity of experimentation necessary.

The nature and breath of the claimed invention encompass engineered bacterium, and method of its use, wherein said bacterium is

- a) any known and unknown bacterium which lacks its own functional *fadB* gene and is transformed to comprise SEQ ID NO: 1, and
- b) wherein said bacterium is transformed with a PHA synthase gene from any natural or man-made source.

While methods of engineering microorganisms for production of chemicals are well developed and skills of artisans high, no one is able to make the claimed invention without Applicants instruction as to the species of bacterium to be used for transformation,

teachings regarding the structure of its *fadB* gene, or a mutant of said bacteria having *fadB* gene inactivated. Furthermore, one skilled in the art is unable to make the

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claimed invention without instructions regarding the structure of PHA synthase gene that is to be used for transformation and the way of performing said transformation.

Provision of transformants of

- 1) *E. coli* wherein the *fadB* gene was deleted by applicants, and *maoC* gene of *E. coli* (SEQ ID NO: 1) and *phaC2_{Ps}* gene of *Pseudomonas* species were introduced, and
- 2) *E. coli* wherein the *fadB* gene was deleted, *maoC* gene was deleted and *maoC* gene of *E. coli* (SEQ ID NO:1) and *phaC2_{Ps}* gene of *Pseudomonas* species introduced,

does not provide the necessary guidance for engineering the broadly claimed transformants. While enablement is not precluded by the necessity for routine screening, if a large amount of experimentation is required, the specification must provide a reasonable amount of guidance with respect to the direction in which the experimentation should proceed so that the claimed method produced a desired product. One skilled in the art cannot produce a bacterium characterized as:

- a) any known and unknown bacteria which lacks its own functional *fadB* gene and is transformed to comprise SEQ ID NO:1, and
 - b) wherein said bacteria is transformed with a PHA synthase gene from any natural or man-made source, because it is out of routine experimentation and has a low probability of success absent teaching of representative number of species of the species of bacteria and structure of PHA synthase genes to be used for transformation.
- The low probability of success is based in the high degree of unpredictability in the art.

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There is a high degree of unpredictability for altering bacteria with an expectation of obtaining a bacterium having the desired characteristics, particularly in view of astronomical number of bacteria and thus their PHA synthase and *fadB* genes. One skilled in the art needs also further instruction as to the details of introduction of any PHA gene to any bacterium, as successful expression of the PHA gene depends at least on the type of expression vector used and the codon usage by the host bacterium. One skilled in the art concludes that without a further guidance on the part of Applicants in regards to detailed instructions as to the species of bacteria, structure of PHA synthase gene and methods of introducing it to said bacterial species, experimentation left to those in the art is improperly extensive and undue.

3. Conclusion

All claims are rejected.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Malgorzata A. Walicka whose telephone number is

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(571) 272-0944. The examiner can normally be reached on Monday-Friday from 10:00 a.m. to 4:30 p.m.

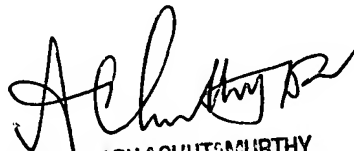
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached on (571) 272-0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Malgorzata A. Walicka, Ph.D.

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Patent Examiner



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